

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0684548	<b>(X3) Date Survey Completed</b>  04/10/2024
<b>Name of Provider or Supplier</b>  Whitesburg Arh	<b>Street Address, City, State</b>  240 Hospital Rd, Whitesburg, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was initiated on 04/09/2024 and concluded on 04/10/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of policy, document review, and confirmed in staff interview; the laboratory director failed to review and approve 8 of 17 required Performance Verification Studies for a Blood Bank test system implemented for patient testing, effective 08/01/2022. Findings included: A review of "Policy No. 2037" titled, "New Method Validation (Qualitative Methods)," dated 11/10/2022, revealed, "NOTE: Before the method is implemented, the Laboratory Director must approve all method implementation data. The statement will read 'This validation study has been reviewed, and the performance of the method is considered acceptable for patient testing'. A copy of the statement will be placed with all the test validation/verification data." A review of ORTHO VISION (MTS Gel) System performance verification records for implementation of the Ortho Vision Gel Blood Bank testing system failed to reveal documentation of review and approval by the laboratory director (LD) of 8 of 17 required performance verification studies prior to the start of patient testing, effective 08/01/2022. During an interview on 04/10/2024 at 9:25 AM, Technical Supervisor (TS) #2 stated the LD was aware of the remaining required performance verification studies, but confirmed there were no signatures or dates to signify the LD's review. During a follow-up interview on 04/10/2024 at 11:25 AM, TS #2 stated the LD left their position prior to completion of the review of all required performance</p>

verification studies and that outstanding studies had not been brought to the attention of the new LD.